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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,785	01/17/2006	Philippe Msika	065691-0430	3623
22428	7590	03/10/2010	EXAMINER	
FOLEY AND LARDNER LLP			GULLEDGE, BRIAN M	
SUITE 500			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,785	Applicant(s) MSIKA ET AL.
	Examiner Brian Guledge	Art Unit 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 October 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4,6-10 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,6-10 and 30-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement (PTO/SB/08)
 Paper No(s)/Mail Date 1/17/06; 3/13/06; 3/29/06.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Change of Examiner

This application has been reassigned from Irina Kosinski to Brian Gullede for the remainder of its prosecution. Applicant is advised that future communications should be directed to Brian Gullede, who can be contacted at 571-270-5756, Monday–Thursday from 6:00 am until 3:00 pm.

Election/Restrictions

Applicant's election of species 3 (a method for improving cicatrisation process, for restructuring the skin and/or mucous membranes, for treating and/or preventing the sagging of the skin and/or mucous membranes) in the reply filed on 30 October 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly added claims 26-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. These claims recite methods that fall within the genus of previously presented and non-elected species 1 (treating or preventing connective tissue degeneration), as demonstrated by previously presented claim 3.

Information Disclosure Statement

The references submitted on the IDS filed on 17 January 2006 were not considered, as the Applicant did not provide a copy of these references. When all the requirements for a national stage application have been completed, applicant is notified (Form PCT/DO/EO/903) of the acceptance of the application under 35 U.S.C. 371, including an itemized list of the items received. The itemized list includes an indication of whether a copy of the international search report and copies of the references cited therein are present in the national stage file. The Examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. See MPEP 1893.03(g). The PCT/DO/EO/903 form mailed 20 June 2006 did not indicate copies of the documents are present, and as such the Examiner did not consider these references.

Claim Rejections - 35 USC § 112, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6-10, and 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating sagging skin, does not reasonably provide enablement for the prevention of sagging skin. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands*

factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state and predictability of the art, and relative skill level:

The claims recite a “method for treating and/or preventing the sagging of the skin.” Thus, the invention relates in part to a method of preventing skin from sagging consisting of the administration of a lupeol-rich extract.

The breadth of the claims: Skin sagging can result from many factors, including aging and extensive loss of weight. The term “preventing” includes prevention of skin sagging from occurring. The term is not limited by any time frame. The claims are thus very broad insofar as they suggest that the skin will not sag when using the claimed extract; or that following administration with this extract, it will not recur. While such “prevention” might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the “real world” in which patients live.

The amount of direction or guidance provided and the presence or absence of working examples: The specification provides no direction or guidance for practicing the claimed invention in its “full scope”. No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing skin sagging, other than that the extract affects the mechanical properties and morphology of fibroblasts. The latter is corroborated by the working examples. The instant disclosure provides no evidence to suggest that this unique activity can be extrapolated to skin sagging generally, and thus does not meet the “how to use” prong of 35 USC 112, first paragraph with regard thereto.

The quantity of experimentation necessary: Because of the known unpredictability of the

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not

art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent skin sagging as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating stretch marks, does not reasonably provide enablement for the prevention and/or delaying of skin aging. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands* (see the above rejection). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state and predictability of the art, and relative skill level:
The claims recite a “method for preventing and/or delaying skin aging.” Thus, the invention relates in part to a method of delaying or preventing the skin from aging, wherein the method consists of the administration of a lupeol-rich extract.

^{“experimentation”.}

The breadth of the claims: All things age with the passage of time. While the skin may not exhibit signs commonly associated with aging at a constant and fixed rate (the appearance of wrinkles can be diminished, for examples), the skin nevertheless ages with each passing second. The claim is not directed to treating signs of aging, or conditions associated with aging, though. The claim is directed to preventing or delaying the skin from aging, and thus if a subject uses the claimed extract, the skin will not age from that point on. Thus the claims encompass ways to stop time, which would necessarily have to occur to stop the skin from aging.

The amount of direction or guidance provided and the presence or absence of working examples: The specification provides no direction or guidance for practicing the claimed invention in its “full scope”. No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing aging or the stoppage of time. Thus, the instant disclosure does not meet the “how to use” prong of 35 USC 112, first paragraph with regard thereto.

The quantity of experimentation necessary: Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent aging as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating stretch marks, does not reasonably provide

enablement for the prevention of stretch marks. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands* (see the above rejection). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state and predictability of the art, and relative skill level: The claims recite a “method for preventing and/or treating stretch marks.” Thus, the invention relates in part to a method of preventing stretch marks consisting of the administration of a lupeol-rich extract.

The breadth of the claims: Stretch marks can result from many factors, mechanical stress (weight gain and weight lifting), hormonal factors (puberty and pregnancy) and corticosteroid therapy. The term “preventing” includes prevention of stretch marks from occurring. The term is not limited by any time frame. The claims are thus very broad insofar as they suggest that the stretch marks will not occur when using the claimed extract; or that following administration with this extract, it will not recur. While such “prevention” might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the “real world” in which patients live.

The amount of direction or guidance provided and the presence or absence of working examples: The specification provides no direction or guidance for practicing the claimed

invention in its "full scope". No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing stretch marks, other than that the extract affects the mechanical properties and morphology of fibroblasts. The latter is corroborated by the working examples. The instant disclosure provides no evidence to suggest that this unique activity can be extrapolated to stretch marks generally, and thus does not meet the "how to use" prong of 35 USC 112, first paragraph with regard thereto.

The quantity of experimentation necessary: Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent stretch marks as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-10, and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "lupeol-rich" in claim 4 is a relative term which renders the claim indefinite. The term "lupeol-rich" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of

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ordinary skill in the art would not be reasonably apprised of the scope of the invention. It can be clearly determined whether a composition is a lupeol extract, but it is unclear what amounts would be considered necessary for the extract to be -lupeol-rich.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6, 9-10, and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) in view of Murad (US Patent 5,972,999). Msika et al. discloses antielastase compositions containing lupine oil (abstract, lines 1-4). In particular, the composition comprises lupine oil in the form of a concentrate (column 2, lines 6-18), and these extracts contain lupeol.² Msika et al. further teaches using this composition as a dermatological product for treating the effects of elastase on the skin by applying the composition comprising the lupine oil concentrate to the skin of the subject (column 2, line 65 – column 3, line 15). Msika et al. does not teach the use of this extract for treating stretch marks, as recited by instant claims 4, 6, and 9.

Murad discloses that the mechanical properties of the skin, such as elasticity, are controlled by the network of collagen and elastic fiber tissue therein (column 1, lines 41-43).

² See US Patent Application Publication 2004/0121030. Note: this reference is not being used substantively as part of the rejection, but rather only to demonstrate an inherent property of white lupine (column 1, line 15) used by Msika et al. This reference discloses that white lupin (same Latin name) contains lupeol (paragraphs [2]-[4]).

Murad further teaches that damaged collagen and elastin lose their contractile properties, and thus lead to such visible signs as stretch marks (column 1, lines 43-48).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the lupine oil-containing composition taught by Msika et al. to treat stretch marks. Msika et al. teaches that the lupine oil composition has antielastase activity, and can be used for treating the effects of elastatase (which breaks down elastase) on the skin, and Murad et al. teaches that damage and loss of elastin leads to stretch marks. Thus, one of ordinary skill, desiring to treat stretch marks, would have used the antielastase composition taught by Msika et al. with reasonable expectation of success.

Msika et al. teaches that the composition comprises from 0.5 to 10 wt% of the lupine oil, which reads on the range recited by instant claim 10. Instant claims 30-32 recite limitations to the amount of lupeol present in the extract that is part of the composition that is applied. Msika et al. discloses that the oil present in the concentrate is up to about 90%, a range that overlaps the instantly recited range. And in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Instant claims 33 and 34 recite limitations to how the lupine-extract was obtained (limiting the plant variety). While Msika et al. does not teach obtaining the extract from these varieties of lupin plants, this does not render the claim patentable. The patentability of the product used does not depend on its method of production, and if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Thus, while

Msika et al. is silent as to the variety of lupin plant used, the composition disclosed by Msika et al. contains the same active ingredient (lupeol) that is instantly recited with regards to the composition.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) and Murad (US Patent 5,972,999) as applied to claim 4 above, and further in view of Hernández-Pérez et al. (*Dermatol. Durg.*, 2002, 28(12), pages 1124-1130).

Msika et al. and Murad teach all of the limitations of instant claim 7 except for the treating of stretch marks for pregnant women. Hernández-Pérez et al. teaches that stretch marks (striae distensae) occur in pregnant women (page 1124, first full paragraph).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the lupine oil composition for treating stretch marks, taught by Msika et al. and Murad, to treat stretch marks on pregnant women, as it was known that this is a patient population that has need for such a treatment.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) and Murad (US Patent 5,972,999) as applied to claim 4 above, and further in view of Herman (US Patent 5,190,979). Msika et al. and Murad teach all of the limitations of instant claim 8 except for the administering the lupeol formulation as a mouthwash. Murad does teach that suitable routes of administration include oral dosage forms, such as solutions (column 8, lines 50-59), but does not teach the specific oral dosage form of a mouthwash.

Herman teaches formulations containing various terpenes, including lupeol (abstract). Herman teaches that these compositions can be administered orally, such as when the composition is formulated as a mouthwash (column 7, lines 45-50).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated the lupeol formulation taught by Msika et al. and Murad as a mouthwash. It was recognized at the time the invention was made that a mouthwash is one type of appropriate formulation for delivering lupeol orally, which is generally taught by Msika et al. and Murad. Generally, it is *prima facie* obvious to select a known material (a lupeol composition) for incorporation into a composition (a mouthwash formulation), based on its recognized suitability for its intended use (dosage form for the oral delivery of lupeol). See MPEP 2144.07.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612